

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

To:

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27. Sep. 2005

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EL: Phase beendet 12.08.05

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22 September 2005 (22.09.2005)

Applicant's or agent's file reference
0000054331

IMPORTANT NOTICE

International application No.
PCT/EP2004/002096

International filing date (day/month/year)
03 March 2004 (03.03.2004)

Priority date (day/month/year)
07 March 2003 (07.03.2003)

Applicant

BASF PLANT SCIENCE GMBH et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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Form PCT/IB/326 (January 2004)

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 0000054331	FOR FURTHER ACTION		See item 4 below
International application No. PCT/EP2004/002096	International filing date (day/month/year) 03 March 2004 (03.03.2004)	Priority date (day/month/year) 07 March 2003 (07.03.2003)	
International Patent Classification (IPC) or national classification and IPC C12N 15/82, 15/29, 15/63			
Applicant BASF PLANT SCIENCE GMBH			

- This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
- This REPORT consists of a total of 10 sheets, including this cover sheet.
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
- This report contains indications relating to the following items:

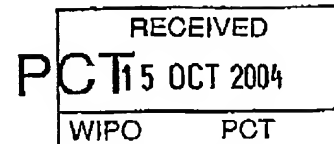
<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input checked="" type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
- The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35 Form PCT/IB/373 (January 2004)	Date of issuance of this report 09 September 2005 (09.09.2005)
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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/002096

International filing date (day/month/year)
03.03.2004

Priority date (day/month/year)
07.03.2003

International Patent Classification (IPC) or both national classification and IPC
C12N15/82, C12N15/29, C12N15/63

Applicant
BASF PLANT SCIENCE GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/002096**Box No. 1 Basis of the opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/002096

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the International filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**International application No.
PCT/EP2004/002096**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 1-7,9-11,16-27 (partially), 8, 13,15 (completely)

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-4,9 (partially) are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
☒ no international search report has been established for the whole application or for said claims Nos. of inventions 2 and 3 (claims 1-7,9-11,16-27 (partially); claims 8,13,15 (completely))

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished
☐ does not comply with the standard

the computer readable form ☐ has not been furnished
☐ does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

 International application No.
PCT/EP2004/002096

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. of invention I (1-7,9-11,16-27 partially; 12,14 completely)

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement

Novelty (N)	Yes: Claims	5-7,12,14,20,21
	No: Claims	1-4,9-11,16-19,22-27
Inventive step (IS)	Yes: Claims	12,14,20,21
	No: Claims	1-7,9-11,16-19,22-27
Industrial applicability (IA)	Yes: Claims	1-7,9-12,14,16-27
	No: Claims	-

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/002096**Re Item III.**

Present claims 1-4 and 9 relate to an extremely large number of possible methods involving starch or amylose biosynthesis enhancing proteins or deficiency or decreased activity thereof. In fact, the claims contain so many options, that a lack of clarity and conciseness within the meaning of Article 6, PCT arises to such an extent as to render a meaningful search of the claims impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear and concise, namely to methods involving starch biosynthesis enhancing proteins as described on page 10, line 10 to page 11, line 10.

Re Item IV.**Requirement of unity:**

The application lacks unity of inventions as required by Article 3(4)(iii) and 17(3)(a), PCT for the following reasons:

The inventions as defined in the enclosed Partial European Search Report relate to various methods of increasing amylose production in plants.

The common concept underlying the present application is that those methods of increasing amylose production in plants all relate to the modulation of proteins involved in starch biosynthesis.

Methods for the modulation (i.e. overexpression and downregulation) of an Arabidopsis glycogenin-like protein (PGSIP) for increased or reduced amylose production in e.g. potato plants is already known in the art (please see WO03014365 page 36, par. 4-page 43, par. 2 and Examples 9,18-20 in connection with SEQ ID NOs:3,7 and 24).

In light of this prior art the above mentioned common concept is not novel and the problem underlying the present application can be redefined as:

The provision of additional methods of increasing amylose production in plants by modulating proteins involved in starch biosynthesis.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/002096

The methods identified in inventions 1 to 3 are different solutions to this problem. Due to the fact that methods of increasing amylose production in plants by modulating proteins involved in starch biosynthesis are known in the prior art and due to the fact that no other technical feature can be distinguished which, in the light of the prior art, could be regarded as a special technical feature in the sense of Rule 13.2, PCT, there is no single general inventive concept underlying the plurality of claimed inventions of the present application in the sense of Rule 13.1, PCT.

Consequently, the application lacks unity of invention and the different inventions are as formulated as follows:

a) Invention I: claims 1-7,9-11,16-27 (partially); claims 12,14 (completely)

A method of increasing the production of starch, a method of producing amylose type starch; nucleic acid sequence SEQ ID NO:1, amino acid sequence SEQ ID NO:2; a transgenic expression cassette, a transgenic host cell and transgenic plants

b) Invention II: claims 1-7,9-11,16-27 (partially); claims 13,15 (completely)

A method of increasing the production of starch, a method of producing amylose type starch; nucleic acid sequence SEQ ID NO:3, amino acid sequence SEQ ID NO:4; a transgenic expression cassette, a transgenic host cell and transgenic plants

c) Invention III: claims 1-3, 9-11 (partially); claim 8 (completely)

A method of increasing the production of starch and a method of producing amylose type starch

It should be noted, that for regrouping the different inventions, the examiner has taken into account the balance between necessary search efforts and the levying of additional fees.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/002096

Re Item V.

1. Novelty and inventive step (Art. 33(2)(3), PCT)

It is pointed out that this Written Opinion only refers to the claims of Invention I as far as these claims have been searched (please see Item III).

The following documents are referred to in this communication:

D1 : WO 03/014365 A (GEMSTAR CAMBRIDGE LTD) 20 February 2003 (2003-02-20)

D2 : WO 94/04693 A (ZENECA LTD.) 3 March 1994 (1994-03-03)

1.1 Invention I of the application relates to methods for increasing starch production, especially amylose production, in plants, by overexpression of a glycogenin gene from *Solanum tuberosum* (StGH1; Examples 5,7 -10,12,14,16,18). Further, a specific glycogenin nucleic acid and amino acid from *Solanum tuberosum* (SEQ ID NO:1,2) as well as an expression cassette comprising sequences with at least 60% identity to SEQ ID NO:1 and fragments thereof, a transgenic host cell and transgenic plants, comprising said expression cassette, are claimed.

1.2 Document D1 discloses methods for increasing the production of starch, especially amylose production, in transgenic plants (e.g. potato plants) by overexpressing glycogenin-like genes (e.g. SEQ ID NO:31; page 4, line 5-page 5, line 24; page 37, line 21-page 38, line 2). One of the glycogenin-like genes of D1 (SEQ ID NO:31) has an identity of 72% in 553 out of 2084 nucleotides to the claimed nucleic acid molecule (SEQ ID NO:1) and the corresponding glycogenin-like protein of D1 (SEQ ID NO:32) displays an identity of 77% in 184 out of 465 amino acids to the claimed glycogenin (SEQ ID NO:2).

In view of D1, the methods for increasing starch production of claims 1-4 and 9-11, as well as the expression cassettes of claims 16-19 and the host cells and transgenic plants of claims 22-27 lack novelty as required by Art. 33(2), PCT. The difference between invention I of the present application and D1 is the use of a different glycogenin gene. It would have been obvious for a person skilled in the art that the method taught in D1 can equally well be carried out with any other

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/002096

gene expressing an active glycogenin, irrespective of a certain sequence identity, if confronted with the problem to increasing starch production in plants. Hence, the subject-matter of claims 1-7, 9-11, 16-19 and 22-27 lacks inventive step with regard to D1 (Art. 33(3), PCT).

- 1.3** D2 also refers to methods for increasing starch or amylose production in plants by overexpression of glycogenin or amylogenin, both proteins which acts as starch synthesis primers (page 4, lines 10-14 page 5, lines 2-15, page 5, line 27-page 6, line 9; page 7, line 30-page 9, line 11). Vectors, host cells and transgenic plants expressing glycogenin or amylogenin are also described (page 69, line 28-page 71, line 23). The amino acid or nucleic acid molecules disclosed in D2 have no relevant sequence identity to the claimed nucleic acids or amino acids. Subject-matter of present claims 1-4 and 9 lacks novelty in view of D2 and subject-matter of claims 1-7, 9-11, 16-18 and 22-27 does not involve an inventive step, since the general principal of increasing starch content of plants by overexpressing glycogenin is known from D2 and the selection of a particular glycogenin gene or protein is considered a non-inventive choice amongst a number of equally suited alternatives.
- 1.4** According to Examples 8 and 9 the StGH1 and StGH2 genes have to be expressed in sense orientation to achieve an increase in starch production. Present claim 19 however relates *inter alia* to an StGH1 and StGH2 antisense construct and claims 25-27 to transgenic plants expressing said antisense construct. Such vectors and plants do not solve the problem of the invention, which is to **increase** (not to decrease) plant starch production (Art. 6, PCT). Hence, subject-matter of claims 19 and 25-27 lack inventive step as far as they refer to antisense expression of glycogenins (Art. 33(3), PCT).

Re Item VIII.

2. Clarity (Art. 6, PCT)

The description contains on page 26, line 14-page 28, line 30 a set of "pseudoclaims" which are broader than the claims on file. This inconsistency between the claims and the description leads to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.